K110102

MAY 13 2011

PREVENTIVE CARE, INC.

510(k) SUMMARY

1. **Submitter:** Preventive Care, Inc.
   15215, Boulder Trail
   Rosemount, MN 55068, USA

2. **Contact Name:** Anil Segat

3. **Phone:** 651 322 9120
4. **Fax:** 651 322 9196
5. **E Mail:** anil@preventivecareinc.com

6. **Date of Preparation:** January 10th, 2011

7. **Device**
   - Trade Name: Powderfree Nitrile Examination Gloves Coated with Allogel®, Blue, Magenta, Copper
   - Common Name: Examination Glove
   - Classification name: Patient Examination Glove (Class1)

8. **Identification of legally marketed devices to which Equivalency is claimed:** Class 1 Powderfree Nitrile Examination Gloves, coated with Allogel®, colored, 80LZA, that meets all the applicable requirements of ASTM D6319-2010 and FDA water leak test

9. **Intended use of device:** Powderfree Nitrile Examination Gloves coated with Allogel®, in colors Blue, Magenta or Copper, is a disposable device worn on the hand of a healthcare or similar personnel, to prevent contamination between the wearer of the glove and the person or substance handled

10. **Summary of technological Characteristics compared to Predicate device:** There are no different technological characteristics compared to the predicate devices (detailed in **Section 2** Form 3514) to which substantial equivalency is sought. They are all non sterile powderfree nitrile examination gloves (one coated with Allogel® Magenta color), with equivalent performance characteristics.

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11. **Performance Data**

Performance data of gloves based on ASTM D6319 and FDA Watertight test

TEST	ASTM D6319 STANDARD REQUIREMENT	POWDER FREE NITRILE EXAM GLOVES COATED WITH ALLOGEL® RESULTS
1. Watertight (1000ml) in accordance with ASTM D 5151	Multiple Normal in accordance with ISO 2859 GI AQL=2.5	Pass GI AQL = 2.5
2. Length (mm) Size XS S M L XL	 Min 220 Min 220 Min 230 Min 230	240 mm minimum for all sizes
3. Palm Width (mm) Size XS S M L XL	 70 ± 10 80 ± 10 95 ± 10 110±10 120±10	 75 – 80 83 – 84 94 – 96 107 – 109 113 – 114
4. Thickness (mm) (Single Layer) Finger Palm Cuff	 Min 0.05 Min 0.05 Min 0.05	 Min 0.12 Min 0.10 Min 0.08
5. Physical Properties In accordance with ASTM D 412 **Before Aging**	 Min 14	 18 – 31

Tensile Strength(MPa) Ultimate Elongation (%) **After Aging** Tensile Strength(MPa) Ultimate Elongation (%)	Min 500 Min 14 Min 400	530 – 600 18 – 29 500 – 550
6. Powder Content in accordance with ASTM D6124	Max 2.0mg/glove	Below 2 mg/glove

A. The performance data of the glove as shown above meets the requirements of ASTM D6319, including the Residual Powder requirement of max 2 mg per glove. Data of an actual representative shipment is detailed in **Section 14**

B. The performance data above show that the Powderfree Nitrile Examination Gloves coated with Allogel®, meet ASTM D 6319 requirements for Dimensions and Tolerances. Data of an actual representative shipment is detailed in **Section 14**

C. The performance data above show that the gloves meet ASTM D 6319 requirements of properties tested in accordance with ASTM D 412. Data of an actual representative shipment is detailed in **Section 14**

D. The Biocompatibility Tests consist of (1) Primary Skin Irritation Test and (2) Guinea Pig Sensitization (Buehler) test. The test reports are detailed in **Sections 8&9**
The gloves have passed the Biocompatibility Test criteria of not being Sensitizers or Irritants.

12. **Conclusion**

We concluded that the Multiple Private Labeled, Powderfree Nitrile Examination Gloves coated with Allogel® in colors Blue, Magenta or Copper meet the requirements of:

- ASTM D-6319 and FDA requirements for:
  - Watertight test for pinholes
  - Physical properties
  - Dimensions
  - Residual Powders

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 13 2011

Ms. Anil Segat
President
Preventive Care, Incorporated
15215 Boulder Trail
Rosemount, Minnesota 55068

Re: K110102
Trade/Device Name: Powder-Free Nitrile Examination Gloves Coated with AlloGel® (Blue/Magenta/Copper)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: March 18, 2011
Received: March 24, 2011

Dear Ms. Segat:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K110102

Device Name: : Powder-Free Nitrile Examination Gloves Coated with AlloGel® (Blue/Magenta/Copper)

Indications for Use:

An examination glove is a disposable device intended for medical and examination purposes that is worn on the examiner's hand to prevent contamination between the examiner and the patient or substance handled

Prescription Use _____ AND/OR Over-The-Counter Use __X_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth T. Claire Will

ivision Sign-Off)

ivision of Anesthesiology, General Hospital

fection Control, Dental Devices

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